Claims

Please amend the claims as follows:

1. (Currently Amended) A pharmaceutical aqueous suspension comprising:

a) a therapeutically effective amount of suspended solid particles in crystal form comprising at least one active ingredient;

b) from about 0.1 to about 0.6 % weight per volume of a thickener, said thickener comprising from about 0.1 to about 0.3% weight per volume of a structuring agent and from greater than 0 up to about 3 % weight per volume of a swelling agent;

c) a uniformly dispersed nucleation inhibitor, wherein said nucleation inhibitor reduces growth rate of said active ingredient compared to suspensions not containing a nucleation inhibitor, wherein said nucleation inhibitor is polyvinylpyrrolidone, and wherein said nucleation inhibitor is present in an amount from ~~above about 0 to about 5 % weight per volume~~ about 1 to about 3 % weight per volume; and

d) at least one amino polycarboxylic acid compound, wherein said amino polycarboxylic acid compound is present in an amount from about ~~0.005 to about 0.1 % weight per volume~~ 0.01 to about 0.05 % weight per volume;

e) from greater than 0 up to about 0.1 % weight per volume of a surfactant;

wherein the pharmaceutical aqueous suspension has a pH of about 3.7 to about 8; and

wherein the amino polycarboxylic acid compound imparts improved pH and viscosity stability to the pharmaceutical aqueous suspension.

2. (Canceled).

3. (Previously Presented) A pharmaceutical aqueous suspension according to claim 1, wherein the suspended solid particles have a median particle size, as measured by laser scattering, of about 1 to about 20 microns.

4. (Canceled).

5. (Previously Presented) A pharmaceutical aqueous suspension according to claim 1, wherein the active ingredient is substantially insoluble in an aqueous environment at room temperature.

6. (Previously Presented) A pharmaceutical aqueous suspension according to claim 1, wherein the pharmaceutical aqueous suspension has a pH between about 3 and about 6 at room temperature.

7. (Canceled).

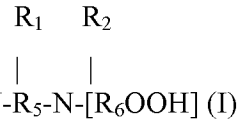
8. (Previously Presented) A pharmaceutical aqueous suspension according to claim 1, wherein the pH of the pharmaceutical aqueous suspension remains within about 0.2 pH units for a period of at least about four weeks when stored at a temperature of at least about 60°C.

9. (Previously Presented) A pharmaceutical aqueous suspension according to claim 1, wherein the viscosity remains constant for at least about two weeks when stored at a temperature of at least about 60°C.

10. (Previously Presented) A pharmaceutical aqueous suspension according to claim 1, wherein the viscosity remains within a range of plus or minus about 25% of its initial value for a period of at least about 8 weeks when stored at a temperature of about 60°C.

11. (Previously Presented) A pharmaceutical aqueous suspension according to claim 1, wherein the at least one amino polycarboxylic acid compound is a compound selected from the group consisting of:

formula (I) and pharmaceutically acceptable salts thereof:



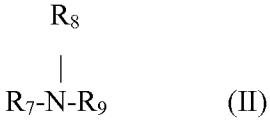
$$[HOOR_4]\text{-}N\text{-}R_5\text{-}N\text{-}[R_6OOH] \quad (I)$$

wherein R_1 and R_2, independently of one another, are hydrogen, hydroxy-terminated C_1-C_4 alkylene, carboxylic-terminated C_1-C_4 alkylene or $N\text{-}[R_3OOH]_m$;

wherein R_3, R_4, R_5 and R_6 independently of one another, are C_1-C_4 alkylene; and

wherein m is 1 or 2;

formula (II)



$$R_7\text{-}N\text{-}R_9 \quad (II)$$

wherein R_7, R_8 and R_9, independently of one another, are hydrogen, C_1-C_4 alkyl, carboxylic-terminated C_1-C_4 alkylene or hydroxy-terminated C_1-C_4 alkylene; and

pharmaceutically acceptable salts of formula (I) or (II).

12. (Previously Presented) A pharmaceutical aqueous suspension according to claim 11, wherein the at least one amino polycarboxylic acid compound is represented by formula (I) and wherein R_1, R_2 and R_3 are ethylene.

13. (Previously Presented) A suspension according to claim 1, wherein the at least one amino polycarboxylic acid compound is selected from the group consisting of ethylenediaminetetraacetic acid (EDTA), hydroxyethylethylenediaminetriacetic acid, dihydroxyethylethylenediaminediacetic acid, 1,3-propanediaminetetraacetic acid, diethylenetriaminepentaacetic acid, triethylenetetraminehexaacetic acid, iminodiacetic acid, methyliminodiacetic acid, nitrilotriacetic acid, salts thereof, and mixtures thereof.

14. (Previously Presented) A suspension according to claim 1, wherein the at least one amino polycarboxylic acid compound is selected from ethylenediaminetetraacetic acid, salts thereof and mixtures thereof.

15. (Previously Presented) A suspension according to claim 1, wherein the amino polycarboxylic acid compound is disodium ethylenediaminetetraacetate.

16. (Previously Presented) A suspension according to claim 11, wherein the active ingredient is an anti-histamine or an analgesic.

17. (Previously Presented) A suspension according to claim 14, wherein the active ingredient is loratadine.

18. (Canceled).

19. (Currently Amended) A pharmaceutical aqueous suspension comprising:

a) a therapeutically effective amount of suspended solid particles in crystal form comprising at least one active ingredient;

b) a blended thickening component comprising from about 0.1 to about 0.3 % weight per volume of xanthan gum and from greater than 0 up to about 3 % pre-gelatinized starch;

c) at least one amino polycarboxylic acid compound, wherein said amino polycarboxylic acid compound is present in an amount from about ~~0.005 to about 0.1 % weight per volume~~ 0.01 to about 0.05 % weight per volume; and

d) polyvinylpyrrolidone wherein said polyvinylpyrrolidone is present in an amount from ~~above about 0 to about 5 % weight per volume~~ about 1 to about 3 % weight per volume;

from greater than 0 up to about 0.1 % weight per volume of a surfactant;

wherein the pharmaceutical aqueous suspension has a pH of about 3.7 to 8; and

wherein the amino polycarboxylic acid compound imparts improved pH and viscosity stability to the pharmaceutical aqueous suspension.

20. (Canceled).

21. (Canceled).

22. (Canceled)..

23. (Previously Presented) A pharmaceutical aqueous suspension of claim 1, wherein said active ingredient is loratadine.

24. (Previously Presented) A pharmaceutical aqueous suspension of claim 19, wherein said active ingredient is loratadine.

25. (Previously Presented) A pharmaceutical aqueous suspension of claim 22, wherein said active ingredient is loratadine.

26. (Currently Amended) The pharmaceutical aqueous suspension of claim 1, wherein said nucleation inhibitor is present in an amount ~~from about 1 to about 3 %~~ of about 2.5 % weight per volume.

27. (Currently Amended) The pharmaceutical aqueous suspension of claim 1, wherein said amino polycarboxylic acid compound is present in an amount from about ~~0.01 to about 0.05 %~~ 0.025 % weight per volume.